

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0695974	(X3) Date Survey Completed 04/05/2018
Name of Provider or Supplier Shoreview Pediatrics Sc	Street Address, City, State 2524 E Webster Place #301, Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with testing personnel, the laboratory did not retain the laboratory's original test results submitted for the urine culture PT samples for event two in 2017. Findings include: 1. Review of PT records showed no evidence of original urine culture PT test results for the second microbiology event of 2017. 2. Interview with testing personnel (staff A) on April 5, 2018 at 10:15 AM confirmed that original urine culture proficiency testing results were not retained.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the manufacturer instructions and laboratory records, and interview with testing personnel, the laboratory does not document the room temperature to ensure storage requirements for the Uricult Cystine Lactose Electrolyte</p>

Deficient/Eosin Methylin Blue (CLED/EMB) urine culture media are met. Findings include: 1. The manufacturer's instructions for the Uricult CLED/EMB urine culture media include directions to store the media between 7 - 25 degrees Celsius. 2. Review of laboratory records shows no documented room temperature records for the laboratory. 3. Interview with testing personnel (staff A) on April 5, 2018 at 11:15 AM confirmed room temperatures are not documented in the area where the Uricult CLED /EMB urine culture media are stored.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory quality control records and interview with testing personnel, the laboratory failed to perform positive and negative quality control materials each day of patient testing for Pertussis, Group A Streptococcus, and Mycoplasma testing performed on the illumigene analyzer, and had not developed an Individualized Quality Control Plan (IQCP). Findings include: 1. Review of quality control records show the laboratory did not perform external quality control each day of patient testing. 2. Interview with testing personnel (staff A) on April 5, 2018 at 10:00 AM confirms the laboratory failed to perform quality control as required for each day of patient testing. Further interview confirmed the laboratory has not established an individualized quality control program consistent with the requirements identified at 493.1256 to function as an equivalent quality control program.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of quality control records and procedures and interview with testing personnel, the laboratory has not checked each batch of Uricult media before or concurrent with the initial use for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. The laboratory has not developed an Individualized Quality Control Plan (IQCP). Findings include: 1. Review of quality control records for the Uricult test system showed no documentation of on-site evaluation of each batch of the media. 2. Review of laboratory procedures showed no evidence of an IQCP for the Uricult test system. 3. Interview with testing personnel (Staff A) on April 5, 2018 at 11:45 AM confirmed

	<p>an IQCP had not been developed for the Uricult test system and that the laboratory did not check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response prior or concurrent with the initial use.</p>
<p>D5785</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of incubator temperature records and interview with testing personnel, the laboratory failed to document corrective action when the documented temperature was not within the established range of 34 to 38 degrees Celsius, which is the laboratory's acceptable range. Findings include: 1. Review of incubator temperature records for July, August, and September 2017 show that 10 out of 67 recorded temperatures were outside of the established range and corrective action was not documented. 2. Interview with the testing personnel (staff A) on April 5, 2018 at 10:45 AM confirmed that the incubator temperature exceeded the established range, as listed above, and corrective action was not documented.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of procedures and performance verification records, observation of testing equipment, and interview with testing personnel, the director, who is also the technical consultant, did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. Performance verification was not evaluated on the second illumigene analyzer before putting the analyzer into use for patient testing. See D6013. 2. The quality control program was not developed to ensure evaluation of the second illumigene analyzer and procedures identifying the type, number and frequency of control testing are not available. Additionally, a procedure to provide equivalent quality testing (an Individualized Quality Control Plan (IQCP)) was not developed prior to reducing the frequency of external quality control testing. See D6020. 3. A procedure for evaluation of testing personnel competency that includes the six assessment criteria for evaluation of competency was not developed. See D6030. 4. Approved laboratory specific procedures for testing performed on the illumigene analyzers are not available to testing personnel. See D6031.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on surveyor review of performance verification records and interview with testing personnel, the laboratory failed to perform verification procedures for the second illumigene analyzer prior to implementation for patient testing. Findings include: 1. Review of performance verification records for the illumigene analyzer show the laboratory did not perform verification procedures including precision and accuracy, before utilizing the second illumigene analyzer for patient testing. 2. Interview with testing personnel (staff A) on April 5, 2018 at 10:45 AM confirmed the laboratory failed to verify the performance of the second illumigene analyzer prior to patient testing starting mid-2017.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor observation of testing equipment, review of procedures, and interview with testing personnel, the laboratory director did not ensure a quality control program was established and maintained for the testing performed on the two illumigene analyzers. Findings include: 1. Observation of testing equipment in the laboratory on April 5, 2018 at 11:00 AM revealed two illumigene analyzers were in use. 2. Interview with testing personnel (staff A) on April 5, 2018 at 11:00 AM revealed monthly quality control testing for each test is performed on one of the two analyzers, but not on both analyzers. 3. Review of test procedures for tests performed on the illumigene analyzers showed for the requirements for quality control, including control number and type, and frequency of testing are not specified. 4. Quality Control testing performed on the illumigene analyzers does not meet the CLIA requirements for testing a known positive and negative sample each day of patient testing and the laboratory did not develop an individualized quality control plan (IQCP) for the test system. See D 5449.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with testing personnel, the laboratory director who is also the technical consultant has not developed a procedure for the evaluation of competency using the six assessment criteria required at 493.1413(b)(8). Findings include: 1. Review of laboratory procedures showed no evidence of a written policy or procedure for the evaluation of testing personnel competency using the six assessment criteria required at 493.1413(b)(8). 2. Interview with testing personnel (staff A) on April 5, 2018 at 9:45 AM confirmed a written policy for evaluation of testing personnel competency has not been developed.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on surveyor review of test procedures and interview with testing personnel, the laboratory director did not ensure current procedures were approved and available for testing performed on the illumigene analyzer. Findings include: 1. Review of the illumigene test procedures showed no indication of approval by the laboratory director. The procedures are not signed or dated. 2. Further review of the illumigene Pertussis procedure shows the procedure is the manufacturer's template procedure for the pertussis assay but has not been completed by the laboratory to provide laboratory specific information. 3. Interview with testing personnel (staff A) on April 5, 2018 at 10:00 AM confirmed the procedure had not been approved by the laboratory director and did not include laboratory specific information.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of personnel evaluation forms and interview with testing personnel, the technical consultant (who is also the laboratory director) has not

evaluated the competency of each testing personnel using the six competency assessment criteria. Findings include: 1. Review of personnel evaluation forms showed no indication of review or evaluation of competency by the technical consultant who is also the laboratory director. The form provides no evidence that the evaluation included the six competency assessment criteria. 2. Interview with testing personnel (staff A) on April 5, 2018 at 9:45 AM confirmed the technical consultant did not evaluate testing personnel competency and the evaluation performed did not include the six assessment criteria.